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APPLICATION NO. 08/0001655	FILING DATE 11/27/97	FIRST NAMED INVENTOR LOFRONZI	ATTORNEY DOCKET NO. 1103326-283
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WHITE & CASE
PATENT DEPARTMENT
1155 AVENUE OF THE AMERICAS
NEW YORK NY 10036-2787

HM42/1127

EXAMINER WEBMAN, E	
ART UNIT 1615	PAPER NUMBER

DATE MAILED: 11/27/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/945655

Applicant(s)

L O FROTH

Examiner

W E B M A W

Group Art Unit

1615

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 10/24/97
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-13 is/are pending in the application.
- ☐ Of the above claim(s) is/are withdrawn from consideration.
- ☐ Claim(s) is/are allowed.
- ☒ Claim(s) 1-13 is/are rejected.
- ☐ Claim(s) is/are objected to.
- ☐ Claim(s) are subject to restriction or election requirement.

Application Papers

- ☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☒ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).
- *Certified copies not received: _____.

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s) _____
- ☒ Notice of References Cited, PTO-892
- ☒ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 5, 6, 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rencher.

Rencher teaches a pharmaceutical delivery vehicle comprising xanthan gum (abstract). Water insoluble materials to retard release are specified (column 3 lines 10-14). (Holesterol lowering agents are disclosed (column 3 line 43).

Applicants stipulate that fluvastatin is known in the art to reduce cholesterol levels (page 4 lines 19-25).

It would have been obvious to one of ordinary skill to deliver fluvastatin in the vehicle of Rencher in view of the fact that the drug is known in the art to reduce cholesterol.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amselem et al. or Sakamoto et al.

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Anselem et al. and Sakamoto et al. teach a vehicle comprising a lipid and fat respectively for delivering water-soluble drugs (Abstract). Waxes and paraffin are specified (column 5 lines 31-34 and column 3 line 32 respectively). Applicants stipulate that fluvastatin is water soluble (page 5 line 7).

It would have been obvious to one of ordinary skill to deliver fluvastatin with the vehicle of Anselem et al. or Sakamoto et al. in view of the fact that fluvastatin is water soluble.

As to the claimed erosion, it is argued that the vehicle melts over time in the manner of a suppository at body temperature. As to the claimed paraffin, Anselem et al. teaches waxes solid at 25 C (column 5 lines 34-35). Paraffin is known to the layman as such a wax.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 7-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kotwal et al. or Eichel et al.

Kotwal et al. and Eichel et al. teach coated vehicles for controlled release of water soluble drugs (Abstracts). Both disclose ethyl cellulose as a coat for controlled release (column 2 line 40 and Abstract respectively).

that fluvastatin is
Applicants stipulate soluble (see above).

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It would have been obvious to deliver fluvastatin with the vehicle of Kotwal et al or Eichel et al. in view of the fact that Fluvastatin is water soluble.

Claims 8, 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 8 'Hydoxpropyl' is indefinite. In claim 12 'including' is non-limiting.

No claims allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number is (703) 308-4432. The examiner can normally be reached on M-F from 9:00 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T. K. Page, can be reached on (703) 308-2927. The fax phone number for this Group is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

E. Webman:jmr

Nov. 17, 1998


EDWARD J. WEBMAN
PRIMARY EXAMINER
GROUP 1500